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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,884	08/27/2007	Karl G. Csaky	NIHA 0383	8820
45160	7590	01/24/2011		
OTT- NIH c/o WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891			EXAMINER AUDET, MAURY A	
			ART UNIT 1654	PAPER NUMBER
			NOTIFICATION DATE 01/24/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

coffice@woodcock.com

Office Action Summary	Application No. 10/588,884	Applicant(s) CSAKY ET AL.	
	Examiner MAURY AUDET	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 30-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-26 and 30-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response are acknowledged.

Election/Restrictions

Applicant's election with traverse of Group III, claims 20-29, as drawn to the elected peptides of SEQ ID NOS: 1-5, in the reply filed on 4/30/10 is acknowledged. The traversal is on the ground(s) that the groups should be kept together under Rule 13.2. This is not found persuasive because, as provided in the restriction, Rule 13.2 permits a combination of a single product, single method of use ("an independent claim for ... a use", not more than one independent claim for more than one use), and a single method of making; but not more than one of any of the three. Here Applicant is claiming two entirely distinct methods of use: treating any condition associated with neovascularization v. treating any cancer.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112 2nd-Maintained

The rejection of claims 22 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive.

Applicant generally relies on caselaw to support his position that the skilled artisan would understand what residues may be modified with D amino acids and maintain have the same utility/function just as the L form. Applicant states:

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"The test for definiteness is whether one skilled in the art would understand **the bounds of the claim when read in light of the specification**. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 [second paragraph] demands no more."~ Definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application disclosure, **the teachings of the prior art**, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.²

There is no definition in the description as to which amino acid residues may be modified to D form and maintain utility/function. The only two passages on D form were:

[0027]The term "peptide" as used herein refers to two or more amino acids linked together via a peptide bond. The amino acids making up a peptide may be any of the 20 standard genetically-encoded amino acids, other naturally occurring amino acids, unnatural amino acids, or chemically derivatized amino acids, and may exist as L form isomers or D form isomers. In addition, the term "peptide" may refer to peptide mimetics or peptides that have undergone a variety of chemical modifications. The present invention utilizes standard notation for peptide sequences, wherein the left end of the molecule is the amino terminal end and the right end is the carboxy terminal end.

[0051]The method of the present invention also encompasses the use of different isomeric forms of the full-length and truncated C16Y peptides. The peptides of the present invention may consist entirely of L form or D form amino acids, or they may consist of some combination of D and L form amino acids. Methods for synthesizing peptides that contain one or more D form amino acids are well-known in the art. Peptides containing one or more D form amino acids are metabolized more slowly and are more resistant to proteolysis than their L form counterparts, primarily because **humans lack the necessary endogenous enzymes to degrade. D form peptides (Fujihara 2000)**. The resultant increase in peptide stability and half-life is likely to increase the therapeutic efficacy of the claimed methods.

Thus, the metes and bounds of the claims are indefinite as read in light of the specification as to what positions in any of the peptides may be substituted with D form

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amino acids. The prior art was not found to recognize this universally. And the current description has not established it as to the presently claimed peptides based on a representative number of tests/data.

Applicant may wish to consider filing a reference that supports that substituting a D amino acid substitution “anywhere” in a peptide will maintain utility.

The rejection is repeated below for continuity of record:

In claims 22 and 24 the terms/phrase "modification" and “comprises one more D form amino acids” are indefinite. What modification? Where? Likewise, which amino acids are to be put into D amino form? In both cases, how and where can such modifications to be made, such that the utility of the peptide is maintained. The Examiner was unable to find a definition for each that answered the issues raised under indefiniteness.

Claim Rejections - 35 USC § 112 1st New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-26 and 30-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. There is no support for the phrase “designated as”, based on a KWIC search of the PGPUB.

Claim Rejections - 35 USC § 112 2nd-New

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-26 and new claims 30-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A new issue on indefiniteness has arisen as to the scope/reach of the metes and bounds of the amended claims.

Applicant has amended in claim 20, what is meant by the transition phrase “designated as”? The MPEP was not found to define where specifically this falls in the 3-tier system of transition phrases (open, semi-open, closed) and related other phrases; but did not that such phrases as "composed of" can be deemed narrow like "consisting of" or given broader meaning under certain circumstances:

OTHER TRANSITIONAL PHRASES

Transitional phrases such as “having” must be interpreted in light of the specification to determine whether open or closed claim language is intended. See, e.g., *Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed.Cir. 2000) (The term “having” was interpreted as open terminology, allowing the inclusion of other components in addition to those recited); *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l Inc.*, 246 F.3d 1336, 1348, 57 USPQ2d 1953, 1959 (Fed. Cir. 2001) (term “having” in transitional phrase “does not create a presumption that the body of the claim is open”); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997) (In the context of a cDNA having a sequence coding for human PI, the term “having” still permitted inclusion of other moieties.). The transitional phrase “composed

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of” has been interpreted in the same manner as either “consisting of” or “consisting essentially of,” depending on the facts of the particular case. See *AFG Industries, Inc. v. Cardinal IG Company*, 239 F.3d 1239, 1245, 57 USPQ2d 1776, 1780-81 (Fed. Cir. 2001) (based on specification and other evidence, “composed of” interpreted in same manner as “consisting essentially of”); *In re Bertsch*, 132 F.2d 1014, 1019-20, 56 USPQ 379, 384 (CCPA 1942) (“Composed of” interpreted in same manner as “consisting of”; however, court further remarked that “the words composed of” may under certain circumstances be given, in patent law, a broader meaning than consisting of.”).

Where does “designated as” fall within the transition phrase spectrum?

The specification provides no support for this phrase or definition (See 112 1st New Matter also)

Allowable Subject Matter

As noted previously, compositions comprising SEQ ID NOS: 1-5 were not found to be reasonably taught or suggested by the prior art of record, based on the ABSS sequence search of the relevant databases for SEQ ID NOS: 1-5, upon addressing the above.

Conclusion

Applicant's amendment (“designated as”) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 1/18/10

/Maury Audet/
Primary Examiner, Art Unit 1654